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INTEGRATIVE THERAPEUTICS INC.

NF Formulas • PhytoPharmica
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 & F: 503.582.0467

ENZYMATIC THERAPY' & PHYTOPHARMICA'

January 10, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Similase is a proprietary blend of vegetarian enzymes that are active across a broad pH range in the digestive tract.* It provides a higher potency and broader range of digestive enzymes than other products.* As a result of the higher potency and broader range of the digestive enzyme activity, Similase provides superior support of carbohydrate, protein, fat, and fiber digestion.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	freeze
-	Robert C. Doster Senior Vice President of Scientific Affairs
Date _	1/10/05

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Similase contains four different porteases to enhance protein digestion in different pH ranges of the digestive tract.* The blend of the four proteases is active in a pH range of 2-10, meaning that this blend is enzymatically active in both the stomach and the intestine.* This range of enzyme activity enhances protein digestion throughout the digestion system.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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	Robert C. Doster Senior Vice President of Scientific Affairs		
Date _	1/10/05		

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825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic) P: 920.469.9099 F: 920.469.4418 (Phyto)

January 10, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	The amylase in Similase is active in a pH range of 4-6, which means that it is active in both the stomach and the intestine.* This range of enzyme activity enhances starch digestion throughout the digestion system.*	Amylase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date <u>1/10/05</u>

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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ENZYMATIC THERAPY' & PHYTOPHARMICA'

January 11, 2005

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	The cellulase in Similase is active in a pH range of 4-6, which means that it is active in both the stomach and the intestine.*	Cellulase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Ву:	KINIL
Title:	Robert C. Doster Senior Vice President of Scientific Affairs
Date _	ilulos

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	The phytase in Similase is active in a pH range of 5-7, which means that it's activity peaks in the intestine.*	Phytase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	- June 1 Mr.
Title:	Robert C. Doster Senior Vice President of Scientific Affairs
Date _	111/05

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ENZYMATIC THERAPY* & PHYTOPHARMICA*

January 12, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE: Label Claims/Disclaimers

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Similase contains three different sugar enzymes to enhance sugar digestion in different pH ranges of the digestive tract.* The blend of the three sugar enzymes is active in a pH range of 3-8, meaning that this blend is enzymatically active in both the stomach and the intestine.* This range of enzyme activity enhances sugar digestion throughout the digestion system.*	Lactase, Sucrase, Maltase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:	fillilt
-	Robert C. Doster
Title:	Senior Vice President of Scientific Affairs
Date	1/12/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Similase contains two different lipases to enhance fat digestion in different pH ranges of the digestive tract.* The blend of the four lipases is active in a pH range of 4-8, meaning that this blend is enzymatically active primarily in the intestine where fat absorption occurs.*	Lipase

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

RUPUL			
Ву:	Robert C. Doster		
Title:	Senior Vice President of Scientific Affairs		
Date _	1/12/05		

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Since digestive enzymes act upon food by breaking it down into simpler components that can be used by the body for energy, digestive enzyme supplementation can be used to enhance the digestive process and ensure complete digestion of food.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Report C Double

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 1/12/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Individuals with carbohydrate intolerance can greatly benefit from supplementing their diet with amylase, sucrase, maltase, and lactase.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

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By:	gy: filest		
Title:	Robert C. Doster Senior Vice President of Scientific Affairs		
Date _	1/12/05		

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely.

Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Supplementing the diet with lactase, amylase, protease, and lipase enzymes will help alleviate the symptoms associated with lactose intolerance.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

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By:	KIRCUL
Title:	Robert C. Doster Senior Vice President of Scientific Affairs
Date _	Vizlos

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Similase®	Digestive enzyme supplementation using amylase, protease, and lipase enzymes can be used to relieve occasional constipation by improving the digestion of food and improving elimination.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

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Title: Senior Vice President of Scientific Affairs

Date 1/12/05

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Similase®	Supplementation with amylase, protease, lipase, cellulase, phytase, sucrase, maltase, and lactase enzymes will provide any missing or insufficient enzymes and alleviate gas symptoms associated with the digestion of food.*	Plant Enzymes: Protease I,II,III,IV, Amylase, Cellulase I,II, Lipase I,II, Phytase, Lactase I,II, Sucrase (Invertase), Maltase (Malt Diastase)

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